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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/881,479 | 06/14/2001 | Scott Adams | 13463-701.202 | 7886 |
| 21971 | 7590 | 04/14/2006 | EXAMINER | |
| WILSON SONSINI GOODRICH & ROSATI 650 PAGE MILL ROAD PALO ALTO, CA 94304-1050 | | | PASS, NATALIE | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3626 | |
| DATE MAILED: 04/14/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 09/881,479 | Applicant(s) ADAMS ET AL. | |
| | Examiner Natalie A. Pass | Art Unit 3626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>2 February 2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 2 February 2006. Claims 1, 10, 12, 36 and 45 have been amended. The IDS statement filed 2 February 2006 has been entered and considered. Claims 1-47 remain pending.

Claim Rejections - 35 USC § 112

2. The rejection of claim 10 under 35 U.S.C. § 112, second paragraph for being indefinite is hereby withdrawn due to the amendment filed 2 February 2006.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 3-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sloane, U.S. Patent Number 5, 619, 991 in view of McMenimen et al., U.S. Patent Application Publication Number 2002/0077850 for substantially the same reasons given in the previous Office Action (paper number 10182005), and further in view of Rapoport et al. U.S. Patent Number 5, 535, 739. Further reasons appear hereinbelow.

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(A) Claim 1 has been amended to recite

- “wherein the test ordering system is configured to enable the in-home test device to be delivered to the patient at the request of the physician” in lines 4-6.

As per these new limitations, Sloane and McMenimen teach a system as analyzed and discussed in the previous Office Action (paper number 10182005).

Sloane and McMenimen fail to explicitly disclose a system wherein the test ordering system is configured to enable the in-home test device to be delivered to the patient at the request of the physician. However, the above features are well-known in the art, as evidenced by Rapoport. In particular, Rapoport teaches

wherein the test ordering system (Rapoport; column 12, lines 12-15) is configured to enable the in-home test device to be delivered to the patient at the request of the physician (Rapoport; column 14, lines 46-57).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Sloane and McMenimen to include these limitations, as taught by Rapoport, with the motivations of generating data that is then analyzed by the physician to determine whether the patient needs a more detailed study or whether therapy should be started (Rapoport; column 15, lines 2-9).

The remainder of claim 1 is rejected for the same reasons given in the prior Office Action (paper number 10182005, section 7, pages 2-7), and incorporated herein.

The motivations for combining the respective teachings of Sloane and McMenimen are as given in the rejection of claim 25 in the prior Office Action (paper number 10182005) and incorporated herein.

(B) Claim 12 has been amended to recite

- “wherein the test distribution and retrieval system is configured to enable the home test unit to be delivered to the patient upon the request of the authorized physician” in lines 7-8.

As per these new limitations, Sloane and McMenimen teach a system as analyzed and discussed in the previous Office Action (paper number 10182005).

Sloane and McMenimen fail to explicitly disclose a system wherein the test distribution and retrieval system is configured to enable the home test unit to be delivered to the patient upon the request of the authorized physician.

However, the above features are well-known in the art, as evidenced by Rapoport.

In particular, Rapoport teaches

wherein the test distribution and retrieval system (Rapoport; column 15, lines 25-26, column 16, lines 23-25) is configured to enable the home test unit to be delivered to the patient upon the request of the authorized physician (Rapoport; column 14, lines 46-57, column 15, lines 25-26, column 16, lines 53-56).

The remainder of claim 12 is rejected for the same reasons given in the prior Office Action (paper number 10182005, section 7, pages 2-8), and incorporated herein.

The motivations for combining the respective teachings of Sloane and McMenimen are as given in the rejection of claim 25 in the prior Office Action (paper number 10182005) and incorporated herein.

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(C) The amendments to claim 10 appear to have been made merely to correct minor typographical or grammatical errors and to correct rejections under 35 U.S.C. §112. While these changes render the language of the claims smoother and more consistent, they otherwise affect neither the scope and breadth of the claims as originally presented nor the manner in which the claims were interpreted by the Examiner when applying prior art within the previous Office Action.

As such, the recited claimed features are rejected for the same reasons given in the prior Office Action (paper number 10182005, section 7, pages 7-8), and incorporated herein.

(D) Claims 3-9, 11, 13-35 have not been amended and are rejected for the same reasons given in the previous Office Action (paper number 10182005, section 7, pages 3-13), and incorporated herein.

5. Claims 36-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sloane, U.S. Patent Number 5, 619, 991 in view of McMenimen et al., U.S. Patent Application Publication Number 2002/0077850 for substantially the same reasons given in the previous Office Action (paper number 10182005). Further reasons appear hereinbelow.

(A) Claim 36 has been amended to recite

- “configured communicate with the database order processing system to enable the medical test device to be delivered to the patient” in lines 5-6.

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As per these new limitations, Sloane and McMenimen teach a system as analyzed and discussed in the previous Office Action (paper number 10182005) further comprising

a logistics system interface configured communicate with the database order processing system to enable the medical test device to be delivered to the patient (McMenimen; paragraphs [0027]-[0028]); Examiner interprets McMenimen's teachings of "[a] customized data set may include, for example, specific functions and/or features ... [...] ... customized shipping parameters, shipping labels, ..." (McMenimen; Abstract) and McMenimen's teachings of "an interactive system in which a manufacturing computer server interacts with various data centers or hubs to collect enabling information for specific build-to-order devices customized to the customer's requirements. The system is interactive with an information management system that is integrally and seamlessly connected with patients, hospitals, sales offices, and related information hubs" (McMenimen; paragraph [0002]) together with McMenimen's teachings of "specific therapeutic and diagnostic options may be included so as to optimize the device for the patient and his/her specific disease state. An individual physician could specify customized shipping parameters. Such customization might even extend to the shipping labels ..." (McMenimen; paragraphs [0027]-[0028] as teaching this limitation.

The remainder of claim 36 is rejected for the same reasons given in the prior Office Action (paper number 10182005, section 7, pages 10-11), and incorporated herein.

The motivations for combining the respective teachings of Sloane and McMenimen are as given in the rejection of claim 25 in the prior Office Action (paper number 10182005) and incorporated herein.

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(B) Claims 37-44 have not been amended and are rejected for the same reasons given in the previous Office Action (paper number 10182005, section 7, pages 10-11), and incorporated herein.

6. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sloane, U.S. Patent Number 5, 619, 991 in view of McMenimen et al., U.S. Patent Application Publication Number 2002/0077850 and Rapoport et al. U.S. Patent Number 5, 535, 739 as applied to claim 1 above, and further in view of Welner, U.S. Patent Number 5, 612, 870 for substantially the same reasons given in the previous Office Action (paper number 10182005). Further reasons appear hereinbelow.

(A) Claim 2 has not been amended and is rejected for the same reasons given in the previous Office Action (paper number 10182005, section 8, pages 13-14), and incorporated herein

7. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sloane, U.S. Patent Number 5, 619, 991 for substantially the same reasons given in the previous Office Action (paper number 10182005), and further in view of Rapoport et al. U.S. Patent Number 5, 535, 739. Further reasons appear hereinbelow.

(A) Claim 45 has been amended to recite

- “device” in the preamble; and

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- “a secure medical test device ordering interface adapted to communicate with the secure test ordering interface to enable the medical test device to be delivered to the patient” in lines 5-6.

As per these new limitations, Sloane teaches an interface to a system as analyzed and discussed in the previous Office Action (paper number 10182005).

Sloane fails to explicitly disclose a secure medical test device ordering interface adapted to communicate with the secure test ordering interface to enable the medical test device to be delivered to the patient.

However, the above features are well-known in the art, as evidenced by Rapoport.

In particular, Rapoport teaches

a secure medical test device ordering interface (Rapoport; column 14, lines 46-57, column 15, lines 25-26, column 16, lines 53-56) adapted to communicate with the secure test ordering interface to enable the medical test device to be delivered to the patient (Rapoport; column 14, lines 46-57, column 15, lines 25-26, column 16, lines 53-56).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Sloane to include these limitations, as taught by Rapoport, with the motivations of efficiently providing an appropriate therapy device that generates data that is then analyzed by the physician to determine whether the patient needs a more detailed study or whether therapy should be started (Rapoport; column 15, lines 2-9, 25-26).

The remainder of claim 45 is rejected for the same reasons given in the prior Office Action (paper number 10182005, section 5, pages 2-3), and incorporated herein.

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8. Claims 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sloane, U.S. Patent Number 5, 619, 991 and Rapoport et al. U.S. Patent Number 5, 535, 739 as applied to claim 45 above, and further in view of McMenimen et al., U.S. Patent Application Publication Number 2002/0077850 for substantially the same reasons given in the previous Office Action (paper number 10182005). Further reasons appear hereinbelow.

(A) Claims 46-47 have not been amended and are rejected for the same reasons given in the previous Office Action (paper number 10182005, section 7, pages 12-13), and incorporated herein

Response to Arguments

9. Applicant's arguments filed 2 February 2006 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 2 February 2006.

(A) Applicant's arguments on pages 9-10 of the response filed 2 February 2006 with respect to claim 45 have been considered but are moot in view of the new ground(s) of rejection.

At pages 10-11 of the 2 February 2006 response, Applicant argues that the claim limitations in the Application are not taught or suggested by the applied references. In response, all of the limitations which Applicant disputes are missing in the applied references, including the newly added limitations, have been fully addressed by the Examiner as either being fully

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disclosed or obvious in view of the combined teachings of the applied references, based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the 35 USC § 103 rejections given in the preceding sections of the present Office Action and in the prior Office Action (paper number 10182005), and incorporated herein. In particular, Examiner notes that the limitations of delivering a test unit to a patient are taught by the applied references. See, for example (Rapoport; column 14, lines 46-57, column 15, lines 25-26, column 16, lines 53-56); in particular, Examiner interprets Rapoport's teachings of "[t]he patient is then given the appropriate therapy device" (Rapoport; column 15, lines 25-26) to be a form of delivering a test unit to a patient.

In response to Applicant's argument at paragraph 3 on page 12 of the 2 February 2006 response that the combined applied references fail to teach limitations in independent claims 1, 12, 25, and 45, Examiner respectfully disagrees. Examiner interprets Rapoport's teachings of "under the present invention, the physician provides the patient with a diagnostic device for use during sleep at home" (Rapoport; column 14, lines 46-57) as teaching the argued limitations.

In response to arguments at paragraph 3 on page 12 regarding claim 36 limitations, Examiner notes that McMenimen teaches "[a] customized data set may include, for example, specific functions and/or features ... [...] ... customized shipping parameters, shipping labels, ..." (McMenimen; Abstract) and McMenimen also teaches "an interactive system in which a manufacturing computer server interacts with various data centers or hubs to collect enabling information for specific build-to-order devices customized to the customer's requirements. The

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system is interactive with an information management system that is integrally and seamlessly connected with patients, hospitals, sales offices, and related information hubs” (McMenimen; paragraph [0002]); and McMenimen teaches “specific therapeutic and diagnostic options may be included so as to optimize the device for the patient and his/her specific disease state. An individual physician could specify customized shipping parameters. Such customization might even extend to the shipping labels ...” (McMenimen; paragraphs [0027]-[0028] Examiner interprets these teachings as teaching “a system interface configured communicate with the database order processing system to enable the medical test device to be delivered to the patient,” as recited in newly amended claim 36.

As per Applicant's argument at paragraph 3 on page 12 of the 2 February 2006 response that there is no motivation to combine the references, the Examiner respectfully submits that obviousness is determined on the basis of the evidence as a whole and the relative persuasiveness of the arguments. See *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Hedges*, 783 F.2d 1038, 1039, 228 USPQ 685,686 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785,788 (Fed. Cir. 1984); and *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143,147 (CCPA 1976).

Using this standard, the Examiner respectfully submits that the burden of presenting a *prima facie* case of obviousness has at least been satisfied, since evidence of corresponding claim elements in the prior art has been presented and since Examiner has expressly articulated the combinations and the motivations for combinations that fairly suggest Applicant's claimed invention (see paper number 06142005). Note, for example, the motivations explicitly stated at

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lines 1-4 of page 5 of the previous Office Action (i.e., " ... with the motivations of providing "a system that has the following goals: ...").

Furthermore, the Examiner recognizes that references cannot be arbitrarily altered or modified and that there must be some reason why one skilled in the art would be motivated to make the proposed modifications. And although the motivation or suggestion to make modifications must be articulated, it is respectfully submitted that there is no requirement that the motivation to make modifications must be expressly articulated within the references themselves. References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures, *In re Bozek*, 163 USPQ 545 (CCPA 1969).

The Examiner is concerned that the Applicant apparently ignores the mandate of the numerous court decisions supporting the position given above. The issue of obviousness is not determined by what the references expressly state but by what they would reasonably suggest to one of ordinary skill in the art, as supported by decisions in *In re Delisle* 406 Fed 1326, 160 USPQ 806; *In re Kell, Terry and Davies* 208 USPQ 871; and *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1988) (citing *In re Lalu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1988)). Further, it was determined in *In re Lamberti et al* 192 USPQ 278 (CCPA) that:

- (i) obvious does not require absolute predictability;
- (ii) non-preferred embodiments of prior art must also be considered; and
- (iii) the question is not express teaching of references but what they would suggest.

According to *In re Jacoby*, 135 USPQ 317 (CCPA 1962), the skilled artisan is presumed to know something more about the art than only what is disclosed in the applied references. In *In*

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re Bode, 193 USPQ 12 (CCPA 1977), every reference relies to some extent on knowledge of persons skilled in the art to complement that which is disclosed therein. In *In re Conrad* 169 USPQ 170 (CCPA), obviousness is not based on express suggestion, but what references taken collectively would suggest.

In the instant case, the Examiner respectfully notes that each and every motivation to combine the applied references is accompanied by select portions of the respective reference which specifically support that particular motivation. As such, it is NOT seen that the Examiner's combination of references is unsupported by the applied prior art of record. Rather, it is respectfully submitted that explanation based on the logic and scientific reasoning of one ordinarily skilled in the art at the time of the invention that support a holding of obviousness has been adequately provided by the motivations and reasons indicated by the Examiner, *Ex parte Levengood* 28 USPQ 2d 1300 (Bd. Pat. App. & Inter., 4/22/93).

As such, it is respectfully submitted that Applicant appears to view the applied references separately, without considering the knowledge of average skill in the art, and further fails to appreciate the breadth of the claim language that is presently recited.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any response to this final action should be mailed to:

Box AF

Commissioner of Patents and Trademarks
Washington D.C. 20231

or faxed to: (571) 273-8300.

For formal communications, please mark
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For informal or draft communications, please label
"PROPOSED" or "DRAFT" on the front page of the
communication and do NOT sign the communication.

After Final communications should be labeled "Box AF."

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Pass whose telephone number is (571) 272-6774. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 6:30 PM. The examiner can also be reached on alternate Fridays.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached at (571) 272-6776. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist whose telephone number is (571) 272-3600. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Natalie A. Pass

April 6, 2006


JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER